Commissioner Charles Smith, Executive Commissioner
Health and Human Services Commission
4900 N. Lamar Blvd.
Austin, TX 78751

Enrique Marquez, Deputy Executive Commissioner
Medical and Social Services Division
4900 N. Lamar Blvd., MC H100
Austin, TX 78751

Stephanie Muth
State Medicaid Director, Medicaid and CHIP Services
4900 N. Lamar Blvd., MC H100
Austin, TX 78751

Dear Commissioner, Deputy Executive Commissioner, and Director,

We write to you as clinicians concerned about an ongoing serious health issue in Texas.

This letter is also submitted on behalf of the Alliance for Patient Access ("AfPA") and its Hepatitis Therapy Access Physicians Working Group ("Physicians Working Group"), and the National Viral Hepatitis Roundtable (NVHR).

AfPA is a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care. The Physicians Working Group is made up of leading practitioners from across the country and came together in 2014 to ensure the perspectives of hepatologists, gastroenterologists, infectious diseases specialists and other clinicians treating patients suffering from hepatitis, are shared with policymakers considering issues impacting access to hepatitis therapies.

NVHR is a national coalition of more than 500 members working together to eliminate hepatitis B and C in the United States. NVHR's vision is a healthier world without hepatitis B and C. NVHR is the largest national coalition of community-based organizations, advocates, healthcare providers, and government and industry partners working together to address hepatitis.

We write to encourage Texas Medicaid to reconsider the current prior authorization policies for the treatment of the hepatitis C virus (HCV). Specifically, the Texas Medicaid Program should reconsider its current prior authorization requirement of a Metavir Fibrosis Score of F3 or F4 for access to curative medical treatments. In effect, this requires patients to advance to liver disease before allowing them to be treated for their disease. In addition to this public health concern, this requirement also causes an undue economic burden to the health system.

The prior authorization policy should be revisited for three basic reasons:

First, and most importantly, the policy has no basis in sound medical practice and is in direct contradiction to the definitive guidelines for care developed by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America ("AASLD/IDSA Guidelines").

Second, as has been clearly articulated by CMS and demonstrated in numerous other states through expensive and needless litigation, the current prior authorization policy violates federal Medicaid law.

Finally, the directly stated assumptions in the state budget process which were the sole basis of support for the current prior authorization policies have turned out to be completely wrong.

We will discuss each in turn.

Prior Authorization -- Fibrosis Score

As physicians, we will address first the issue we feel should be dispositive of the discussion and the issue on which we have the most personal experience and expertise. The current prior authorization policy needlessly endangers patient health and needlessly endangers public health as well.

First, on the individual patient level, it appears to be the view of some that those with a fibrosis score below F3 have plenty of time before the disease has any impact on them or others. In short, these patients have time to wait. That is simply not the case for many reasons.

Setting aside the novel medical concept that an available treatment that can avoid physical damage to a patient should await the occurrence of the physical damage before allowing access to the treatment, liver fibrosis is not the sole complication of HCV. All of the following are also potential symptoms with HCV: fever, fatigue, loss of appetite, nausea, vomiting, abdominal pain, and joint pain. These potential physical manifestations are in addition to the patient knowingly living with a contagious condition of deadly potential – that can be cured.

The "it can wait" philosophy also ignores the reality that liver disease progression in HCV patients is not a predictable, straight-line event. It is recognized in this practice area that some patients do not progress while others rapidly develop significant fibrosis. While some of the factors that are related to rate of progression are known, there is no way to predict the progression rate for any particular patient. Also, the "it can wait" approach completely ignores the critical issue of hepatocellular cancer (HCC), which has the highest age-adjusted incidence in Texas. HCC rates continue to increase whereas other cancer rates are decreasing. HCV is the leading cause of HCC and the only proven method to effectively prevent HCC is to treat HCV. However, this treatment must occur at an early stage. The current Medicaid policy of waiting until patients have F3 and F4 puts them at risk for HCC. It is worth noting that the Cancer Prevention and Research Institute of Texas (CPRIT) -- funded by state legislation to curb the incidence of cancers in Texas -- has made HCC prevention a top priority. It would certainly seem that Medicaid should be aligned with that critical public health goal.

Second, the current prior authorization policy needlessly endangers public health. No matter what the rate of liver damage progression is or the presence of other symptoms and the day-to-day of living with a dangerous yet curable disease, the simple reality remains that the patient is contagious until cured. This involves all kinds of potential transfers of the disease, including potential vertical transmission to

infants. Further, the extremely unfortunate and dangerous reality of the opioid crisis which our state and nation currently face makes the presence of contagious individuals all the more dangerous to the public health. This issue is becoming so acute that the National Academies of Science just held a two day seminar devoted to the topic:

http://nationalacademies.org/hmd/Activities/PublicHealth/IntegratingInfectiousDiseaseConsiderationswithResponsetotheOpioidEpidemic.aspx

As physicians who see the medical impacts – both to individuals and the public health -- of the current prior authorization policy up close every day, we urge you to bring the Medicaid policy into alignment with the accepted and definitive medical guidelines for treatment in this area.

Medicaid Law Requires Treatment

While we are not lawyers, we would ask that you consult with Medicaid law experts on the consistency between the current prior authorization policy and federal requirements.

Well over two years ago, CMS issued a letter to the states with a direct warning about prior authorization policies inconsistent with sound medical practice:https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-172.pdf

Since that time, multiple states have found themselves defending expensive lawsuits because their prior authorization policies were in conflict with federal law. Universally, those suits have resulted in the states moving towards access policies more in line with sound medical practice.

Given CMS directly called this issue out to the states so long ago, one would suspect patience with Medicaid programs that have not moved into compliance is near an end with regulators and potential plaintiffs. We urge Texas not proceed down a route that will only result in funds wasted on expensive litigation when we should be treating patients and protecting the public health.

Prior Authorization Policy Directly Based On Flawed Assumptions

During the adoption process of the current Texas budget, in setting specific budget assumptions for the Medicaid program in general and hepatitis C treatment specifically, the Legislative Budget Board wrote the following:

Similarly, advances in treatment for the hepatitis C virus (HCV) are resulting in increased costs for CMHC. Assuming the number of patients treated for HCV remains similar to previous years, ***cost for the treatment of this population may increase as newer, more expensive therapies are approved.*** *In November 2015, CMHC implemented changes in treatment protocol in an effort to control costs associated with the development and availability of new HCV drugs by prioritizing patients for treatment based on severity of disease. CMHC updated its disease management guide for HCV, requiring that a patient meet certain advanced-stage clinical criteria before receiving treatment. This change in treatment protocol resulted in a decrease in the number of patients with HCV that receive treatment. For fiscal year 2016, CMHC provided treatment for 833 HCV patients at a drug cost of $3.1 million, compared*

to 2,532 HCV patients for fiscal year 2015 at a drug cost of $2.0 million. Changes such as this increased cost are considered by UTMB and TTUHSC in the development of their estimate of upcoming resource needs.

See Page 373-374 of the Legislative Budget Board Staff Reports (emphasis added): http://www.lbb.state.tx.us/documents/publications/staff_report/3729_lbb_staff_reports.pdf

In reality, the exact opposite has occurred versus what was assumed when the Medicaid budget was adopted. Since the above was written and the state's Medicaid budget was adopted based upon those assumptions, it is true that newer therapies have been introduced. However, the costs of those newer therapies are dramatically lower than the cost of the some of the previous therapies, and that has had the effect of lowering the cost of all therapies in this area (just as CMS correctly predicted in its 2015 letter to the states.)

While we must note as physicians we find the idea of utilizing prior authorizations as a fiscal rationing tool – unrelated to any legitimate medical considerations – as highly objectionable on many levels, the fiscal reality is clear that the budget assumption were wrong, and therefore the policies driven by those underlying assumption should be revisited.

Conclusion

On behalf of ourselves and other like-minded clinicians in Texas, the AfPA and its Hepatitis Therapy Access Physicians Working Group, and the NVHR, we urge you to seriously reconsider and revise the current prior authorization policy for treatment of hepatitis C in Texas. We thank you for your attention to these important issues and would be pleased to meet with you to discuss this matter further or provide any further information that may be useful.

Sincerely,

Alliance for Patient Access

National Viral Hepatitis Roundtable

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